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10/761,481	01/20/2004	Nozer M. Mehta	133302-546280/US	2921
67395	7590	11/02/2011	EXAMINER	
GREENBERG TRAURIG (NJ)			RUSSEL, JEFFREY E	
200 PARK AVE.				
P.O. BOX 677			ART UNIT	
FLORHAM PARK, NJ 07932			PAPER NUMBER	
			1654	
			NOTIFICATION DATE	
			DELIVERY MODE	
			11/02/2011	
			ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Art Unit: 1654

1. The proposed new claim limitations at claim 1, last four lines, and at claim 45, last three lines, raise new issues which would require further consideration and search. The proposed new claim limitations were not present in the previous versions of the claims. It is not clear that merely reciting an improved result, i.e. enhanced bioavailability and absorption, is sufficient in and of itself to overcome a prima facie case of obviousness. As noted earlier during prosecution of the application (see, e.g., the Office action mailed September 18, 2009, pages 16 and 17), Applicants have established an unexpected increase in bioavailability for orally administered PTH 1-34NH<sub>2</sub> compared to non-amidated PTH 1-34. However, Applicants have not demonstrated equivalent results for any other species encompassed by the claims, and unexpected results for a single species is not considered to be commensurate in scope with the claims. Further, it is noted that the proposed new claim limitations do not specify a degree of enhancement, and even evidence of unexpected results does not automatically rebut a prima facie case of obviousness. See *Agrizap Inc. v. Woodstream Corp.*, 520 F3d 1337, 86 USPQ2d 1110 (Fed. Cir. 2008). For example, it is not clear that any degree of enhancement outweighs the expected increase in oral bioavailability due to the use of Stern et al's and the WO Patent Application 02/043767's excipients/carriers.

The proposed amendment to claim 1 requiring the oral pharmaceutical composition to be in the form of a tablet or capsule would have been entered if submitted separately, and would have overcome the anticipation rejection based upon the Neugebauer et al article (Biochemistry, Vol. 34, pages 8835-8842).

2. The proposed amendment to claim 45 is not in compliance with 37 CFR 1.121(c)(2) because not all changes to the claim are accurately marked with bracketing and/or underlining.

In particular, the paragraph labels “(A)” and “(B)” have been omitted without marking. It is not clear if the omissions were intentional or not.

In proposed claim 1, line 4, “an” (second occurrence) should probably be changed to “the” (so as to refer to the active peptide agent first recited at line 2 of the claim).

In proposed claim 45, page 7 of the amendment filed October 24, 2011, line 2, “physiologically” should be inserted before “active peptide” so as to be consistent with the terminology used at claim 45, line 2.

3. The final Office action mailed August 24, 2011 incorrectly lists the status of claim 42 and 60. Claims 42 and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The examiner apologizes for any confusion his error may have caused. It should be noted that claims 42 and 60 are novel and unobvious over the prior art of record regardless of whether the proposed new amendments to claims 1 and 45 are entered.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/  
Primary Examiner, Art Unit 1654

JRussel  
October 28, 2011